

STERILE WATER- water injection
General Injectables and Vaccines, Inc.

Sterile Water for Injection, USP
Glass Vial
Plastic Vial
Rx Only

EN-3405
946300012

DESCRIPTION

This preparation is designed solely for parenteral use only after addition of drugs that require dilution or must be dissolved in an aqueous vehicle prior to injection.

Sterile Water for Injection, USP is a sterile, nonpyrogenic preparation of water for injection which contains no bacteriostat, antimicrobial agent or added buffer and is supplied only in single-dose containers to dilute or dissolve drugs for injection. For I.V. injection, add sufficient solute to make an approximately isotonic solution.

Water for Injection, USP is chemically designated H₂O.

The glass vial is Type I or II borosilicate glass and meets the requirements of the powdered glass test according to the USP standards.

The semi-rigid vial is fabricated from a specially formulated polyolefin. It is a copolymer of ethylene and propylene. The safety of the plastic has been confirmed by tests in animals according to USP biological standards for plastic containers. The container requires no vapor barrier to maintain the proper labeled volume.

CLINICAL PHARMACOLOGY

Water is an essential constituent of all body tissues and accounts for approximately 70% of total body weight. Average normal adult daily requirement ranges from two to three liters (1.0 to 1.5 liters each for insensible water loss by perspiration and urine production).

Water balance is maintained by various regulatory mechanisms. Water for distribution depends primarily on the concentration of electrolytes in the body compartments and sodium (Na⁺) plays a major role in maintaining physiologic equilibrium.

The small volume of fluid provided by Sterile Water for Injection, USP when used only as a pharmaceutical aid for diluting or dissolving drugs for parenteral injection, is unlikely to exert a significant effect on fluid balance except possibly in neonates or very small infants.

INDICATIONS AND USAGE

This parenteral preparation is indicated only for diluting or dissolving drugs for

intravenous, intramuscular or subcutaneous injection, according to instructions of the manufacturer of the drug to be administered.

CONTRAINDICATIONS

Sterile Water for Injection, USP must be made approximately isotonic prior to use.

WARNINGS

Intravenous administration of Sterile Water for Injection without a solute may result in hemolysis.

PRECAUTIONS

Do not use for intravenous injection unless the osmolar concentration of additives results in an approximate isotonic admixture.

Consult the manufacturer's instructions for choice of vehicle, appropriate dilution or volume for dissolving the drugs to be injected, including the route and rate of injection.

Inspect reconstituted (diluted or dissolved) drugs for clarity (if soluble) and freedom from unexpected precipitation or discoloration prior to administration.

Pregnancy Category C. Animal reproduction studies have not been conducted with Sterile Water for Injection. It is also not known whether sterile water containing additives can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sterile Water for Injection with additives should be given to a pregnant woman only if clearly needed.

Pediatric Use

Safety and effectiveness have been established in pediatric patients. However, in neonates or very small infants the volume of fluid may affect fluid and electrolyte balance.

Drug Interactions

Some drugs for injection may be incompatible in a given vehicle, or when combined in the same vehicle or in a vehicle containing benzyl alcohol. Consult with pharmacist, if available.

Use aseptic technique for single or multiple entry and withdrawal from all containers.

When diluting or dissolving drugs, mix thoroughly and use promptly.

Do not store reconstituted solutions of drugs for injection unless otherwise directed by the manufacturer of the solute.

Do not use unless the solution is clear and seal intact. Do not reuse single-dose containers. Discard unused portion.

ADVERSE REACTIONS

Reactions which may occur because of this solution, added drugs or the technique of

reconstitution or administration include febrile response, local tenderness, abscess, tissue necrosis or infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection and extravasation.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate countermeasures, and if possible, retrieve and save the remainder of the unused vehicle for examination.

OVERDOSAGE

Use only as a diluent or solvent. This parenteral preparation is unlikely to pose a threat of fluid overload except possibly in neonates or very small infants. In the event these should occur, re-evaluate the patient and institute appropriate corrective measures. See **WARNINGS, PRECAUTIONS** and **ADVERSE REACTIONS**.

DOSAGE AND ADMINISTRATION

The volume of the preparation to be used for diluting or dissolving any drug for injection is dependent on the vehicle concentration, dose and route of administration as recommended by the manufacturer.

This parenteral should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

Sterile Water for Injection, USP is supplied in the following:

Unit of Sale	Total Content
NDC 0409-4887-05 Tray of 25 Single-dose Glass Fliptop Vials	1 mL
NDC 0409-4887-10 Tray of 25 Single-dose Plastic Fliptop Vials	10 mL
NDC 0409-4887-34 Tray of 30 Single-dose Plastic Fliptop Vials	10 mL
NDC 0409-4887-20 Tray of 25 Single-dose Plastic Fliptop Vials	20 mL
NDC 0409-4887-50 Tray of 25 Single-dose Plastic Fliptop Vials	50 mL
NDC 0409-4887-99 Case of 25 Single-dose Glass Fliptop Vials	100 mL

Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.]

Distributed by Hospira, Inc., Lake Forest, IL 60045 USA

LAB-1292-2.0

Revised: 05/2021

Sample Package Label

NDC # 52584-079-25
ITEM# :2480738
LOT # XXXXXXXXX
EXP : mm - dd - yy

Packaged By
General Injectables and Vaccines, Inc
80 Summit View Lane
Bastian, VA 24314


STERILE WATER
100 mL
INJECTION, USP
SINGLE DOSE

SEE MANUFACTURER'S INSERT
FOR COMPLETE PRODUCT AND
PRESCRIBING INFORMATION

FOR DRUG DILUENT USE ONLY. DO NOT GIVE
INTRAVENOUSLY UNLESS RENDERED NEARLY ISOTONIC.
STERILE. NONPYROGENIC. CONTAINS NO ANTIMICROBIAL
OR OTHER ADDED SUBSTANCE. PROTECT FROM FREEZING.
WARNINGS: NOT ISOTONIC, HEMOLYTIC.
Keep out of
children's reach.

Store at controlled room
temperature 68F to 77F.

MANUFACTURER INFORMATION
Mfr: Hospira
ORIG MFG LOT: XX - XXX - XX
NDC:0409 - 4887 - 99



(10)XXXXXX
(17)XXXXXXXX
(01)XXXXXXXXXXXX
(21)XXXXXXXXXXXX
RX ONLY

STERILE WATER

water injection

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:52584-079(NDC:0409-4887)
Route of Administration	INTRAMUSCULAR, INTRAVENOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
WATER (UNII: 059QF0KO0R) (WATER - UNII:059QF0KO0R)	WATER	1 mL in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52584-079-25	1 in 1 BAG	07/03/2018	10/01/2024
1		100 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA018801	07/03/2018	10/01/2024

Labeler - General Injectables and Vaccines, Inc. (108250663)

Revised: 12/2022

General Injectables and Vaccines, Inc.